

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Rockville MD 20857

JUN 2 4 1999

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The Honorable Paul S. Sarbanes United States Senate Washington, D.C. 20510-2002

Dear Senator Sarbanes:

Thank you for your letter of June 9, 1999, on behalf of your constituent, Ms. Ann-Wallis White of Annapolis, Maryland, concerning the petition for a performance standard for Vibrio vulnificus in shellfish filed with the Food and Drug Administration (FDA or the Agency) by the Center for Science in the Public Interest (CSPI). As you may know, FDA published a request for comments on this petition in the <u>Federal</u> Register of January 21, 1999. We have enclosed a copy for your reference.

Ms. White opposes required pasteurization of seafood because it would have a destructive effect on waterfront communities and industries. She encourages FDA to work with the Interstate Shellfish Sanitation Conference (ISSC) in addressing this proposal.

We appreciate your bringing your constituent's comments to our attention and we have entered them into the Administrative Record for this petition. They will be reviewed in the Agency's deliberations on this petition.

We trust this information responds to your concerns. Please contact us if we may be of further assistance in this matter.

Sincerely,

n Melinda K. Plaisier

Interim Associate Commissioner for Legislative Affairs

Enclosure

cc: Dockets Management Branch (Docket No. 98P-0504)

98P-0504

-260/Ans

United States Senate

WASHINGTON, DC 20510-2002

June 9, 1999

Ms. Diane Thompson
Associate Commissioner For Legislative Affairs
Food and Drug Administration, DHHS
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Thompson:

Enclosed is a copy of correspondence I received from Ms. Ann-Wallis White. The letter raises some serious concerns about the pasteurization of seafood. I would certainly appreciate it if you would carefully review this matter and provide me with an appropriate response.

Your attention to this matter is greatly appreciated.

With best regards,

Sincerely,

Paul Sarbanes

United States Senator

PSS/alv

No: 99- 4094



ann-wallis white charter yacht consultant post box 4100, annapolis, md. 21403 fax 410-263-0399

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Please find attached my letter to the FDA regarding the DANGEROUS petition it is considering to force the pasteurization of ALL seafood.

This could be devasating for the Bay and the people who work it, to say nothing of all other waterfront communities throughout the country.

Please let me know your position on this immediately, as the matter is being acted upon April 21st.

Sincerely,

ann-wallis white

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ann-wallis white charter yacht consultant post box 4100, annapolis, md. 21403 fax 410-263-0399



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For problems in transmittal, please call 410-263-6366

Docket # 98P-0504

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Mr. William K. Hubbard
Dockets Management Branch - HFA-305
Food & Drug Administration
5630 Fishers Lane, #1061
Rockville, MD. 20852

Dear Sir,

The proposed requirement of pasteurization of seafood in response to petitions by the Science in the Public Interest group is a simplistic "solution" to a more complex issue, which has far-reaching destructive effects on waterfront communities and industries all over the country.

It is imperative that the matter is given more complete attention, as many of these same communities were nearly destroyed by another ill-considered piece of Federal regulation, the "luxury tax" on boats -- which only served to bankrupt an American Industry and its' workers, and fatten the purses of European & Oriental boat builders.

There is an organization in place, the INTERSTATE SHELLFISH SANITATION CONFERENCE, which is prepared to assist in more properly dealing and researching with this issue. We encourage you to consider the matter more fully.

The FDA permits the ingestion, inhalation, etc.. of substances much more likely to KILL you than a DISCRETIONARILY consumed piece of uncocked seafood. This is discriminatory, ill-considered, and capitulation to noisy factions who do not consider the entire picture. This could destroy whole communities of watermen, and for NO GOOD REASON. Please suggest to the CSPI that they cook their own seafood, not mine.

I exhort you to reconsider this matter in a broader perspective, and take no regulatory steps at this time.

Sincerely, Oxwarte